Application No.: 10/658,116 Docket No.: BVTP-P02-004

REMARKS

Claims 1 and 27-35 are pending.

Applicants note that the IDSs filed on 1/12/04, 8/9/04, and 10/17/05 have been considered by the Examiner.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

Specification

The Examiner requests Applicants to update the priority paragraph on page 1. Applicants have amended the priority paragraph to obviate this objection.

Claim rejections under 35 U.S.C. § 112, first paragraph

The Office Action rejects Claims 29-35 under 35 U.S.C. 112, first paragraph, for allegedly lacking enablement, because there is allegedly no disclosure of a "syringe adaptor housing."

Applicants submit that "syringe adaptor housing" is referred to in the originally filed specification (see page 5, line 24 of the original specification). This term has been amended to "syringe adaptor (200)" by the September 8, 2003 Preliminary Amendment. Thus to avoid any potential confusion, Applicants have amended Claim 29 to recite "syringe adaptor" to obviate this rejection. Applicants submit that the amendment does not narrow the scope of the claim.

Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph are respectfully requested.

Claim rejections under 35 U.S.C. § 102

Claims 1 and 27-32 are rejected under 35 U.S.C. § 102(e), as allegedly being anticipated by Weston (U.S. Pat. No. 5,891,086, or "Weston1").

Applicants have amended Claim 1 to further clarify the subject matter claimed. Support for "gas generated by the propellant" can be found, for example, on page 6, last paragraph.

Support for "through the first cavity and the second cavity" can be found throughout the specification, *see*, for example, page 7, the 2nd through the 4th paragraphs, and Figure 3.

Applicants submit that Weston1 cannot anticipate Claim 1 and its dependent claims, because Weston1 at least fails to disclose, among other things, the <u>propellant</u>, the <u>piston</u> having <u>a first cavity</u>, and that the gas travel <u>through the first cavity and the second cavity</u>.

Specifically, the Examiner alleges that the high pressure gas chamber 117 in Figure 11 of Weston1 is the claimed "propellant." However, the instant specification clearly uses the term "propellant" to means a gas-generating charge. The Examiner's interpretation distorts the meaning of the term "propellant" to the extent that it is neither reasonable nor consistent with the specification, thus in direct violation of the "broadest reasonable interpretation" standard mandated by the Patent Office and sanctioned by the Federal Circuit. See Phillips v. AWH Corp., 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005), holding that pending claims during patent examination must be "given their broadest reasonable interpretation consistent with the specification." (emphasis added). Also see MPEP 2111.

The Examiner also alleges that piston 102 / 104 has a first cavity. But the Examiner never points out where in Figure 11 is that "first cavity." Weston1 refers to 102 as a "ram," and there is no disclosure in Weston1 that suggests the ram has any cavity therein. Clarification is respectfully requested. The Examiner also alleges that the piston has one hole. The Examiner does not explain, and Applicants are unable to identify where in the ram 102 is the "hole." Clarification is respectfully requested.

Finally, amended Claim 1 requires a gas generated by the propellant to travel through the first and the second cavities. There being no identified first cavity in Weston1, this claim limitation is also not met.

Thus Weston1 cannot anticipate Claim 1 and its dependent claims. Reconsideration and withdrawal of the rejections are respectfully requested.

Applicants further submit that Weston1 cannot anticipate Claim 29 and its dependent claims, because Weston1 at least fails to disclose, among other things, a <u>syringe adaptor</u> having an <u>outer vent sleeve</u>, the <u>at least one relief hole</u> on the movable piston, *etc*.

Specifically, the Examiner argues that notch 47 in Figure 9a of Weston1 is a "relief hole." However, notch 47 is apparently a mechanism to hold rod / piston 48 in place by latch 26.

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Applicants do not understand how a "notch" can be interpreted as a "hole" in any sense of the word. Clarification is respectfully requested.

In addition, Applicants do not understand, and respectfully disagree with the Examiner's interpretation of latch 26 as the <u>syringe adaptor</u> of the claimed invention. Clarification is respectfully requested.

There are numerous other dissimilarities between the claimed device and the Weston1 device shown in Figure 9a, Applicants reserve the right to argue these differences, if necessary, in future responses.

Claims 1 and 27-28 are also rejected under 35 U.S.C. § 102(e), as allegedly being anticipated by Weston (U.S. Pat. No. 6,620,135, or "Weston2").

Applicants submit that Weston2 cannot anticipate Claim 1 and its dependent claims, because Weston2 at least fails to disclose, among other things, the <u>propellant</u>, a piston having <u>a</u> <u>first cavity</u> and <u>one hole</u>, and that the gas travel <u>through the first cavity and the second cavity</u>.

Again, the Examiner alleges that the high pressure gas 8 in gas cylinder 1 of Figure 1 is the claimed "propellant." As argued above, the instant specification clearly uses the term "propellant" to means a gas-generating charge, rather than a high pressure gas pre-filled in a gas cylinder. The Examiner's interpretation is neither reasonable nor consistent with the specification, and is squarely at odds with the "broadest reasonable interpretation" standard mandated by the Patent Office and sanctioned by the Federal Circuit. See Phillips v. AWH Corp., 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). Also see MPEP 2111.

Secondly, the Examiner alleges that piston 3 has a first cavity as recited in the claims. But the Examiner fails to point out where in piston 3 is the first cavity. It appears that piston 3 is a solid rod, and there is no reason or advantage to have any cavities in piston 3 based on its mechanism of operation. In addition, contrary to the Examiner's assertion, there is not any holes in piston 3. Applicants wish to bring the Examiner's attention to col. 4, lines 3-6, where the specification (of Weston2) explicitly states that "[t]he positions of the holes are also indicated in FIG. 1. But it must be understood that the holes are in the cylinder 1, not, as might be thought from FIG. 1, in the piston 3." (emphasis added)

Finally, amended Claim 1 requires a gas generated by the propellant to travel through the

first and the second cavities. There being no identified first cavity in Weston2, this claim limitation is also not met.

Thus Weston2 cannot anticipate Claim 1 and its dependent claims. Reconsideration and withdrawal of the rejections are respectfully requested.

Claims 1 and 27-28 are also rejected under 35 U.S.C. § 102(e), as allegedly being anticipated by Jacobsen (U.S. Pat. No. 6,045,534, or "Jacobsen").

Applicants submit that Jacobsen cannot anticipate Claim 1 and its dependent claims, because the Jacobsen device does not meet the limitation that requires a gas generated by the propellant to travel through the first cavity and the second cavity.

According to the Examiner, the Jacobsen device has a piston 16 having a first cavity, which presumably is the drug capsule 18 in Figure 2A. The Examiner also argues that plunger 20 is the hollow sleeve with a second cavity. Assuming for the sake of argument that the space trapped between the wedged plunger surface and membrane 21 is the "second cavity," the gas generated by propellant 58 clearly cannot travel through the first cavity and the second cavity. In fact, the gas can never get into either the first or the second cavity.

Therefore, Jacobsen cannot anticipate Claim 1 and its dependent claims. Reconsideration and withdrawal of the rejections are respectfully requested.

Double Patenting

Claims 1 and 27-35 are rejected on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1-23 of U.S. Pat. No. 6,616,627, because the conflicting claims are allegedly not patentably distinct from each other.

Applicants submit that, pursuant to 37 C.F.R. § 1.130(b), a timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome the double patenting rejection. Applicants will submit a terminal disclaimer, as appropriate, upon indication of allowable subject matter.

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CONCLUSION

For the foregoing reasons, Applicants believe that the claims are now in condition for allowance and early notification to this effect is earnestly solicited. Any questions arising from this submission may be directed to the undersigned at (617) 951-7000.

Applicants believe no fee in addition to those listed in the accompanying amendment transmittal (filed concurrently herewith) is due with this response. However, if any other fee is due, please charge our Deposit Account No. 18-1945, from which the undersigned is authorized to draw under Order No. BVTP-P02-004.

Dated: November 2, 2007

Respectfully sylomitted,

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